

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicants: Herbert M. Dean et al.
Title: CARDIOPROTECTIVE DOSAGE UNITS
Atty. Dkt. No.: dean0404con
Art Unit: 1614
Examiner: Donna A. Jagoe

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Commissioner for Patents
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DECLARATION OF ROBERT E. WEINSTEIN, M.D.

I, Robert E. Weinstein, M.D., hereby declare the following:

1. I am a 67 year-old physician whose professional activities have included nine years of medical training and greater than twenty years of practice in the subspecialty of Allergy and Clinical Immunology. My professional credentials include certifications by the American Board of Internal Medicine and the American Board of Allergy and Clinical Immunology. I am a Fellow of the American College of Allergy and Clinical Immunology.

2. My subspecialty practice of Allergy and Clinical Immunology focused upon the diagnosis and treatment of respiratory disorders such as asthma, skin disorders such as angioedema and urticaria, and also drug reactions, which may manifest as respiratory or skin problems. My curriculum vitae is attached (Exhibit A-rew806).

3. Greater than 75% of patients I treated were referred to me by other physicians.

4. In the course of my experience, I was asked by other physicians to consult on patients with cough thought to be due to asthma or another respiratory disorder, and I found that the cough was due to the patient's taking an ACE inhibitor. This was not an uncommon event, happening many times a year.

5. In the course of practice, I was also asked to consult on patients having swelling, and found that the problem was due to an ACE inhibitor.

6. On a number of occasions, I have also noticed an acquaintance or relative coughing, and, being attuned to respiratory disease and drug reactions, diagnosed it as being due to an ACE inhibitor, whereas the individual's physician had not.

7. It is my impression from these experiences that reactions to ACE inhibitors may often be overlooked or missed by practitioners. I believe that, in some instances, the connection is not made simply because it isn't foremost in the practitioner's mind, and in others, it may be consequent to the complexity of the patient's medical problems and/or multiplicity of treatments that the individual is receiving. Regardless of the reason, the medical literature supports that ACE inhibitor reactions are overlooked, and sometimes may be severe. (See Exhibits 01-83006 to 12-83006 submitted with the Response After Final Action of even date herewith).

Declarant further states that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: August 30, 1996

Name: 
Robert E. Weinstein, M.D.

Exhibit A-rew806

Robert E. Weinstein, M.D.
CEO, J-MED Pharmaceuticals, Inc.
Medical Curriculum Vitae

School: Tufts University School of Medicine, M.D. 1964
Internship: Maimonides Hospital 1964-65
Residency: Henry Ford Hospital, Internal Medicine 1965-68
Military: Chief Medical Services, Perrin AFB 1968-70
Fellowship: Henry Ford Hospital, Department of Allergy 1970-71
Practice: Private Allergy Practice 1971-74
Henry Ford Hospital, Department of Allergy 1974-76
Private Practice, Allergy and Clinical Immunology 1976-92
Board Certification: American Board of Internal Medicine 1972
American Board of Allergy and Clinical Immunology 1975
Hospital Affiliations: Chief, Section of Allergy and Clinical Immunology, Providence Hospital,
Southfield, Michigan 1976-92
Director, Medical Education, Providence Hospital 1976-79.
Consultant, Henry Ford Hospital, Department of Allergy 1976-86
Staff Physician, William Beaumont Hospital, Royal Oak, Michigan 1976-92
Acknowledgments: Peer Survey, Detroit Monthly 1992: "300 Best Physicians"
Business Interests: CEO, J-MED Pharmaceuticals 1992-present
Societies: Fellow, American College of Allergy and Clinical Immunology
American Academy of Allergy
Massachusetts Medical Society

Publications/Presentations:

1. Weinstein RE, Anderson J, Kvale P, and Sweet LC. Effects of humidification on exercise-induced asthma. *Journal of Allergy and Clinical Immunology* 57:250-251, 1976.
2. Weinstein RE, Bond BH, and Silberberg BK. Tissue ferritin concentration in carcinoma of the breast. *Cancer* 50:2406-2409, 1982.
3. Weinstein RE, Bond BH, and Silberberg BK. Correlation of tissue ferritin concentration and histopathology. in *Breast Cancer. 3rd Annual Breast Cancer Symposium*, San Antonio, Texas, 1982.
4. Weinstein RE. Exercise-induced asthma. *Ear, Nose and Throat Journal* 63:57-65, 1984.
5. Vaughn CB, Weinstein RE, Bond MS, Rice R, Vaughn RW, McKendrick A, Ayad G, Rockwell MA, and Rocchio R. Ferritin content in human cancerous and non-cancerous colon tissue. *Cancer Investigation*, 5(1):7-10, 1987.

Exhibit A-rew806

6. Weinstein RE and Pieper DR. Altered cerebral dominance in an atopic population. *Brain, Behavior and Immunity* 2:235-241, 1988.
7. Weinstein RE, Bond BH, Silberberg BK, Vaughn CB, Perla, S, and Pieper DR. Tissue ferritin concentration and prognosis in carcinoma of the breast. *Breast Cancer Research and Treatment* 14: 349-353, 1989.
8. Ferrari, JR, Weinstein, RE, Loboeki, CA, and Pieper, DR. Tissue ferritin levels as an independent tumor marker in early stages of breast cancer. *American College of Physicians*, September, 1989.
9. Ferrari, JR, Weinstein, RE, Loboeki, CA, and Pieper, DR. Tissue ferritin levels as an independent tumor marker in early stages of breast cancer. *Michigan State Medical Society*, November 1989.
10. Weinstein RE and Pieper DR. Altered cerebral dominance in an atopic population. *American College of Allergy and Immunology*, November, 1989 .
11. Weinstein RE, Gurvitz M, Weinstein AM, Solomon W, and Pieper DR. Altered cerebral dominance in children of asthmatic mothers. *American Academy of Allergy and Immunology*, March, 1990.
12. Weinstein RE, Gurvitz M, Weinstein AM, Solomon W, Perla, S, and Pieper DR. Cerebral dominance in atopy and in children of asthmatic mothers. *1st International Congress: International Society for Neuroimmunomodulation*. Florence, Italy, May, 1990.
13. Weinstein RE and Pieper DR. Cerebral dominance in atopy. *MSMS*. April 1990.
14. Chiodo E, Weinstein RE and Pieper DR. Cerebral dominance in atopy. *ACOP*, Mich. November, 1990.
15. Weinstein RE. Handedness, hormones and allergies. *Midwest Forum on Allergy*. February 1991.
16. Caradonna V, Weinstein RE, and Pieper DR. Return of sense of smell in a patient with nasal polyposis following estrogen therapy. *MSMS*, April 1991.
17. Weinstein RE, Loboeki, C, Owenby, D. and Pieper DR. Association of elevated cord blood IgE with altered steroidogenesis. *Journal of Allergy and Clinical Immunology* 87:334, 1991.
18. Caradonna V, Weinstein RE, and Pieper DR. Allergic rhinitis following bone marrow transplantation. *ACOP*, Michigan 1991.
19. Weinstein RE, Gurvitz M, Greenberg, D, Weinstein AM, Solomon W, Perla, S, and Pieper DR. Cerebral dominance in atopy and in children of asthmatic mothers. *Annals New York Academy of Science*, 650:25-29, 1993.
20. Weinstein RE, Loboeki, CA, and Pieper DR. Allergy and the Geshwind-Behan-Galaburda Model. *Brain and Cognition* 26:181-184, 1994.
21. Weinstein RE, Loboeki, CA, Gravett S, Hum H, Negrich R, Herbst J, Greenberg D, Gurvitz M, Greenberg, D, and Pieper DR. Decreased adrenal sex steroid levels in the absence of glucocorticoid suppression in postmenopausal asthmatic women. *Journal of Allergy & Clinical Immunology* 97:1-8, 1996.

Exhibit A-rew806

22. Weinstein RE, O'Brien S, and Weinstein AM. A regimen of chlorpheniramine at night and pseudoephedrine during the day for allergic rhinitis; Comparison with fexofenadine twice daily. American College of Allergy, November 1997.
23. Malaczynski JK, Loboeki CA, Sardesai S, Weinstein RE, and Drelichman A. Correlation of mutant p53 expression with other prognostic indicators in breast cancer. AACR, April 1998.

Ongoing scientific interests:

1. Treatment systems for allergic diseases
2. Physiology of exercise-induced asthma
3. Hormonal influences on development of allergy
4. Immunoregulation of breast cancer